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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,287	02/06/2007	Noboru Sakaguchi	1422-0719PUS1	3172

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FALLS CHURCH, VA 22040-0747

EXAMINER
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HOFFMAN, SUSAN COE

ART UNIT	PAPER NUMBER
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1655

NOTIFICATION DATE	DELIVERY MODE
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07/06/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/581,287	<b>Applicant(s)</b> SAKAGUCHI ET AL.	
	<b>Examiner</b> Susan Coe Hoffman	<b>Art Unit</b> 1655	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2009 and 22 April 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 17-19 and 21-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 17, 19 and 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18 and 24-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

1. The amendment filed December 9, 2009 has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 5-16 and 20 have been cancelled in this amendment.
3. Claims 24-36 have been added in this amendment.
4. Claims 1-4, 17-19 and 21-36 are pending.

### ***Election/Restrictions***

5. In the reply filed on July 14, 2009, applicant elected Group XII, now claims 18 and 24-36, with traverse.
6. Applicant's election with traverse of water and ethanol for species A and filtration for species B in the reply filed on April 22, 2010 is acknowledged. The traversal is on the ground(s) that a search of all of the species could be done without undue burden. This is not found persuasive because the species each require separate consideration and search. Thus, a search of all of the species would be burdensome.

The requirement is still deemed proper and is therefore made FINAL.

7. Claims 1-4, 17, 19 and 21-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.
8. Claims 18 and 24-36 are examined on the merits.

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***Claim Rejections - 35 USC § 112***

9. Claims 27, 28 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are indefinite because it is unclear what degrees of dissolution are encompassed by "essentially completely" dissolved. Thus, the metes and bounds of the claims are unclear.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 18 and 24-36 rejected under 35 U.S.C. 103(a) as being unpatentable over Liu (CN 1278433 - translation) in view of Bordia (Indian Heart Journal (1985), vol. 37, no. 3, pp. 179-182).

Liu teaches a method for treating atherosclerosis using an extract from *Phyllanthus emblica* (amla). The extract inhibits fibrin formation (see page 4 of the translation). The extract is formulated into oral dosage forms such as liquid preparations and tablets (see page 7 of the translation). The extract is made using aqueous ethanol on dried, pulverized plant material. The extracts are dried to remove the solvent and further solvent extracted (see claim 1, pages 6, 7 and 18 of the translation). The reference also teaches using filtration to purify extracts (see page 16 of the translation).

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The reference does not specifically teach using lyophilization during the drying step. However, lyophilization is a well known technique to use to dry extracted substances. Thus, an artisan of ordinary skill would reasonably expect that lyophilization could be usefully employed to perform the drying step taught in the reference. Based on this reasonable expectation of success, the artisan would have been motivated to modify the extraction procedure of the reference to include the use of lyophilization.

The reference does not specifically teach pulverizing the plant to a mesh size of 40 or smaller. However, the particle size of pulverized plant material would be obvious to optimize because it is known in the art that exposing more surface area allows for improved extraction efficiency. Thus, an artisan would have been motivated to modify the pulverized particles taught in the reference to use a particle size of 40 mesh or smaller.

The reference also does not specifically teach using alma fruit as the source of the extract. However, Bordia teaches using amla fruit to inhibit atherosclerosis by enhancement of fibrinolytic activity (see page 181). Enhanced fibrinolysis would lead to an inhibition in fibrin formation. Thus, an artisan of ordinary skill would reasonably expect that alma fruit could be used in the method taught in Liu because Bordia teaches that the fruit is also able to treat atherosclerosis by acting on fibrin formation. This reasonable expectation of success would motivate the artisan to modify Liu to include the use of amla fruit as the source of the extract.

The references do not specifically teach that the extract has the dissolution characteristics claimed. However, since the references together teach making an amla fruit extract in the same manner as claimed by applicant, the reference extract would intrinsically have the same physical characteristics as applicant's claimed extract.

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11. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Coe Hoffman/  
Primary Examiner, Art Unit 1655